



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
-----------------	-------------	----------------------	---------------------	------------------

10/572,664

03/20/2006

Jonathan Robert Rhoades

8502-US

4631

29157 7590
K&L Gates LLP
P.O. Box 1135
CHICAGO, IL 60690

06/19/2009

EXAMINER

OLSON, ERIC

ART UNIT

PAPER NUMBER

1623

NOTIFICATION DATE

DELIVERY MODE

06/19/2009

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

chicago.patents@klgates.com

Office Action Summary	Application No.	Applicant(s)	
	10/572,664	RHOADES ET AL.	
	Examiner	Art Unit	
	ERIC S. OLSON	1623	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 11 March 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☐ Claim(s) 12, 13, 16-21, 24, 25 and 27-31 is/are pending in the application.
- 4a) Of the above claim(s) 27 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 12, 13, 16-21, 25 and 28-31 is/are rejected.
- 7) ☒ Claim(s) 24 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

Detailed Action

This office action is a response to applicant's communication submitted March 11, 2009 wherein claims 12, 13, 16, 18, 19, 21, 24, 25, 28, and 29 are amended, claims 14, 15, 22, 23, and 26 are cancelled, and new claim 31 is introduced. This application is a national stage application of PCT/EP04/10496, filed September 17, 2004, which claims priority to foreign application GB0321996.1, filed September 19, 2003.

Claims 12, 13, 16-21, 24, 25, and 27-31 are pending in this application.

Claims 12, 13, 16-21, 24, 25, and 28-31 as amended are examined on the merits herein.

Applicant's amendment, submitted March 11, 2009, with respect to the rejection of instant claims 12-14, 16-18, 25, 26, and 28-30 under 35 USC 102(e) for being anticipated by Einarsson et al., has been fully considered and found to be persuasive to remove the rejection as the claims have been amended to require that the oligosaccharide be present in an amount of between 2.5-10% of the composition. Therefore the rejection is withdrawn.

Applicant's amendment, submitted March 11, 2009, with respect to the rejection of instant claims 12-14, 16-18, 25, 26, and 28-30 under 35 USC 102(e) for being anticipated by Takaichi et al., has been fully considered and found to be persuasive to remove the rejection as the claims have been amended to require that the

Art Unit: 1623

oligosaccharide be present in an amount of between 2.5-10% of the composition.

Therefore the rejection is withdrawn.

Applicant's amendment, submitted March 11, 2009, with respect to the rejection of instant claims 12-14, 16-18, 24, 25, and 28-30 under 35 USC 102(e) for being anticipated by Bindels et al., has been fully considered and found to be persuasive to remove the rejection as the claims have been amended to require that the oligosaccharide be present in an amount of between 2.5-10% of the composition. Therefore the rejection is withdrawn.

Applicant's amendment, submitted March 11, 2009, with respect to the rejection of instant claims 12-14, 16-18, 25, and 28-30 under 35 USC 102(b) for being anticipated by Nesser et al., has been fully considered and found to be persuasive to remove the rejection as the claims have been amended to delete casein glycomacropeptide from the claims. Therefore the rejection is withdrawn.

Applicant's amendment, submitted March 11, 2009, with respect to the rejection of instant claim 15 under 35 USC 103(a) for being obvious over Bindels et al., has been fully considered and found to be persuasive to remove the rejection as claim 15 has been cancelled. Therefore the rejection is withdrawn.

Art Unit: 1623

Applicant's amendment, submitted March 11, 2009, with respect to the rejection of instant claims 12, 13, 16-20, 29, and 30 under 35 USC 102(b) for being anticipated by Baillon et al., has been fully considered and found to be persuasive to remove the rejection as the claims have been amended to no longer include lactosucrose.

Therefore the rejection is withdrawn.

Applicant's amendment, submitted March 11, 2009, with respect to the rejection of instant claims 12-17 and 24 under 35 USC 102(b) for being anticipated by Yokoyama et al., has been fully considered and found to be persuasive to remove the rejection as the claims have been amended to require that the oligosaccharide be present in an amount of between 2.5-10% of the composition. Therefore the rejection is withdrawn.

The following new grounds of rejection are introduced:

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claim 31 is rejected under 35 U.S.C. 102(e) as being anticipated by Angstrom et al. (PCT international publication WO2004/002495, included with PTO-892)

Angstrom et al. discloses a composition containing a pathogen binding oligosaccharide. (p. 8 lines 13-16) These compositions are useful for treating infections, such as diarrhea, due to pathogenic *E. coli* and *Helicobacter* species. (p. 9 lines 10-31) The compositions can additionally include probiotic bacteria and prebiotic oligosaccharides including chitosan. (p. 85 lines 6-30) Therefore Angstrom et al. anticipates the claimed invention. Note that the claims do not define a specific chain length for chito-oligosaccharides. Therefore prior art mentions of chitosan fall within this group.

Claims 12, 13, 16-18 and 28-30 are rejected under 35 U.S.C. 102(b) as being anticipated by Patrick et al. (Reference included with PTO-892)

Patrick et al. discloses a study of the effect of partially hydrolyzed guar gum on constipation in a population of elderly nursing home residents. (p. 913 left column second paragraph) The subjects were administered a composition of 4g PHGG in 4 oz fluid, gradually increased to 12g. (p. 913 left column fifth paragraph) As 4 oz is about 113g and 4 fluid oz of water is about 118g, the lowest 4g dose was administered in a composition comprising about 3.4% of PHGG by weight, and the highest dose of 12g was about 10.1-10.6% PHGG. These amounts are reasonably considered to be “about 2.5 to about 10%” according to the instant claims. Therefore the compositions meet the requirements of the instant claims, and the process of adding the PHGG to the fluid is

Art Unit: 1623

considered to anticipate the methods of claims 28-30. Although Patrick et al. does not explicitly disclose that the compositions are for inhibiting or treating enteral infections of pathogenic bacteria, this property is inherent in any composition containing the recited ingredients. Furthermore administering said compositions to a subject inherently reduces and inhibits invasion or infection of said pathogenic bacteria in any mammal it is administered to, as said mammal will have a reduced likelihood of contracting an enteric bacterial infection. Therefore Patrick et al. anticipates the claimed invention.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claim 31 is rejected under 35 U.S.C. 103(a) as being unpatentable over Lee et al. (Reference included with PTO-892) in view of Prieto et al. (US patent 5906982, of record in previous action)

Lee et al. discloses the growth of bacterial cultures in the presence of chitooligosaccharides. (p. 320 left column paragraph 4 - right column paragraph 2) The chitooligosaccharides stimulate the growth of bifidobacteria. (p. 321 right paragraph section 3.3)

Prieto et al. discloses a nutritional formulation that is effective for stimulating the growth of bacteria of the genus *Bifidobacterium*. (column 2 lines 1-13) This formulation

Art Unit: 1623

can be used to inhibit infection with bacterial species such as Bacteroides, Clostridium, and E. coli. (column 4 lines 5-15)

It would have been obvious to one of ordinary skill in the art at the time of the invention to administer the chitooligosaccharides described by Lee et al. to a patient suffering from an enteric bacterial infection. One of ordinary skill in the art would have been motivated to do so because Prieto et al. already discloses using a different Bifidobacterium-enhancing prebiotic composition for the same purpose. One of ordinary skill in the art would reasonably have expected success because it is well recognized in the art that one known composition can be substituted for another known composition having the same disclosed function and utility.

Therefore the invention taken as a whole is *prima facie* obvious.

Claims 12, 16-18, 25, and 28-30 are rejected under 35 U.S.C. 103(a) as unpatentable over Bindels et al. (US patent 6863918, of record in previous action)

Bindels et al. discloses an infant formula. (column 2 lines 47-54) One component of the infant formula is a prebiotic component such as isomalto-oligosaccharides. (column 15 lines 23-36) Because the claims do not define how long an oligosaccharide has to be in order to be considered a long chain oligosaccharide, this oligosaccharide is considered to be long chain isomalto-oligosaccharide. In one preferred embodiment, these oligosaccharides have between 2-20 sugar residues and connected by alpha-1,6 linkages. (column 15 lines 16-22) In a preferred composition, component C (the prebiotic) is present in a range of from 3-15% of the composition. (column 5 lines 8-19)

Art Unit: 1623

Examples are given for these compositions and methods of making them. (column 16 line 60 - column 18 line 59) A study is also disclosed in which infants were fed the disclosed formula, resulting in a decrease in symptoms such as constipation, abdominal discomfort, and minor gastrointestinal problems. (column 18 line 65 - column 19 line 7) Although Bindels et al. does not explicitly disclose compositions for inhibiting or treating enteral infections of pathogenic bacteria, this property is inherent in any composition containing the recited ingredients. Furthermore administering said compositions to a subject inherently reduces and inhibits invasion or infection of said pathogenic bacteria in any mammal it is administered to, as said mammal will have a reduced likelihood of contracting an enteric bacterial infection. Bindels et al. does not explicitly disclose a range of about 2.5-10% oligosaccharide.

It would have been obvious to one of ordinary skill in the art at the time of the invention to prepare and administer the compositions of Bindels et al. with between 3 and 10% oligosaccharide. When the claimed ranges “overlap or lie inside ranges disclosed by the prior art” a prima facie case of obviousness exists. See *In re Wertheim*, 541 F.2d 257, 191 USPQ 90 (CCPA 1976); *In re Woodruff*, 919 F.2d 1575, 16 USPQ2d 1934 (Fed. Cir. 1990). See MPEP § 2144.05 [R-1]. Thus one of ordinary skill in the art would have been motivated to make and use compositions having this range of oligosaccharide, and would have reasonably expected success in doing so.

Therefore the invention taken as a whole is *prima facie* obvious.

The following rejections of record in the previous action are maintained:

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 12-13, 16-18, 25, and 28-30 are rejected under 35 U.S.C. 102(b) as being anticipated by Tuohy et al. (of record in previous action)

Tuohy et al. discloses a study of the effects of PHGG (partially hydrolyzed guar gum) and FOS (fructooligosaccharide) on gut microflora in humans. (p. 342, right column second paragraph - p. 343 right column first paragraph) The PHGG was administered as biscuits that contained 11% PHGG. This amount is reasonably considered to be "about 10%" as recited in the instant claims. This study constitutes a method comprising administering PHGG to subjects according to the instant claims. Furthermore the prebiotics were supplied as biscuits which are reasonably considered to be a pharmaceutical or nutritional composition according to the claimed invention. Subjects receiving the prebiotic treatment increased the levels of *bifidobacterium* in their intestines. (p. 344, left column and tables 1 and 2) Although Tuohy et al. does not explicitly disclose compositions for inhibiting or treating enteral infections of pathogenic bacteria, this property is inherent in any composition containing the recited ingredients. Furthermore administering said compositions to a subject inherently reduces and inhibits invasion or infection of said pathogenic bacteria in any mammal it is

Art Unit: 1623

administered to, as said mammal will have a reduced likelihood of contracting an enteric bacterial infection. Therefore Tuohy et al. anticipates the claimed invention.

Response to Argument: Applicant's arguments, submitted March 11, 2009, have been fully considered as they relate to the above ground of rejection, and not found to be persuasive to remove the rejection. Applicant argues that Tuohy et al. does not disclose compositions containing from about 2.5% to about 10% of PHGG. However, in the context of the recipe given by Tuohy et al., 11% PHGG is reasonably considered to be "about 10%." In a recipe for a food or nutraceutical product, a difference of 10% in either direction for an ingredient such as dietary fiber is not critical. Therefore the rejection is deemed proper and maintained.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 19-21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Tuohy et al. (of record in previous action) as applied to claims 12-14, 16-18, 25, and 28-30 above, and further in view of Prieto et al. (US patent 5906982, of record in previous action)

The disclosure of Tuohy et al. is discussed above. Tuohy et al. does not disclose a method comprising administering the disclosed composition to a subject suffering from a pathogenic bacteria-associated enteric disorder.

Prieto et al. discloses a nutritional formulation that is effective for stimulating the growth of bacteria of the genus *Bifidobacterium*. (column 2 lines 1-13) This formulation can be used to inhibit infection with bacterial species such as *Bacteroides*, *Clostridium*, and *E. coli*. (column 4 lines 5-15)

It would have been obvious to one of ordinary skill in the art at the time of the invention to administer the biscuits described by Tuohy et al. to a patient suffering from an enteric bacterial infection. One of ordinary skill in the art would have been motivated to do so because Prieto et al. already discloses using a different *Bifidobacterium*-enhancing prebiotic composition for the same purpose. One of ordinary skill in the art would reasonably have expected success because it is well recognized in the art that one known composition can be substituted for another known composition having the same disclosed function and utility.

Therefore the invention taken as a whole is *prima facie* obvious.

Response to Argument: Applicant's arguments, submitted March 11, 2009, have been fully considered as they relate to the above ground of rejection, and not found to be persuasive to remove the rejection. Applicant argues that Tuohy et al. does not disclose compositions containing from about 2.5% to about 10% of PHGG. However, in the context of the recipe given by Tuohy et al., 11% PHGG is reasonably considered to be "about 10%." In a recipe for a food or nutraceutical product, a difference of 10% in

Art Unit: 1623

either direction for an ingredient such as dietary fiber is not critical. Furthermore, even if it were allowed, for the sake of argument, that the amount of 11% PHGG is not about 10%, one of ordinary skill in the art would still have been able to vary the amount of PHGG in the biscuits to optimize the amount and arrive at the claimed invention. It is ordinary and routine in the art to adjust the amount of an active ingredient in order to arrive at the optimal proportion of ingredients. Therefore the rejection is deemed proper and maintained.

Claims 19-21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bindels et al. (US patent 6863918, of record in previous action) as applied to claims 12-18, 25, and 28-30 above, and further in view of Reid et al. (US patent 5906982, of record in previous action)

The disclosure of Bindels et al. is discussed above. Bindels et al. does not disclose a method comprising administering the disclosed composition to a subject suffering from a pathogenic bacteria-associated enteric disorder.

Reid et al. discloses probiotic therapies for the treatment and inhibition of intestinal infection in newborns. (column 2 lines 47-59) Probiotic organisms having this beneficial effect include bacteria of the genus Bifidobacteria. (column 3 lines 8-19) Infections that can be reduced or eliminated in this manner include bacterial pathogens such as *Clostridium*, *Escherichia*, *Kelbsiella*, *Salmonella*, *Shigella*, *Campylobacter*, *Pseudomonas*, *Streptococcus*, *Enterococcus*, *Staphylococcus*, and other species.

Art Unit: 1623

(column 4 lines 10-19) These species are infectious agents in infectious diarrhea among infants. (column 1 lines 27-42)

It would have been obvious to one of ordinary skill in the art at the time of the invention to administer the infant formula described by Bindels et al. to a newborn suffering from an enteric bacterial infection. One of ordinary skill in the art would have been motivated to do so because Reid et al. already discloses treating the same disorders by improving the population of bifidobacteria in the intestine. The two therapies, the probiotic therapy of Reid et al. and the prebiotic therapy of Bindels et al. are directed toward producing the same effect (increased bifidobacterial population) in the same subject population. (infants) One of ordinary skill in the art would reasonably have expected success because it is well recognized in the art that one known composition can be substituted for another known composition having the same disclosed function and utility.

Therefore the invention taken as a whole is *prima facie* obvious.

Response to Argument: Applicant's arguments, submitted March 11, 2009, have been fully considered as they relate to the above ground of rejection, and not found to be persuasive to remove the rejection. Applicant argues that Bindels et al. does not disclose prebiotic compositions containing any of the three oligosaccharides remaining in the claims, namely methyl manno-oligosaccharides, partially hydrolyzed guar gum, and long chain isomalto-oligosaccharides. However, as discussed in the rejection over Bindels et al. alone, in the absence of a definition of "long chain" that defines how long the oligosaccharide chain must be, the isomaltooligosaccharides disclosed by Bindels et

Art Unit: 1623

al. are reasonably considered to fit the requirements of this claim language. Therefore the rejections is maintained.

Conclusion

Claims 12, 13, 16-21, 25, and 28-31 are rejected. Claim 24 is objected to for depending from a rejected base claim but would be allowable if rewritten in independent form incorporating all the limitations of the rejected base claim and any intervening claims.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ERIC S. OLSON whose telephone number is (571)272-9051. The examiner can normally be reached on Monday-Friday, 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Shaojia Anna Jiang can be reached on (571)272-0627. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 1623

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Eric S Olson/
Examiner, Art Unit 1623
6/10/2009